DECLARATION AND POWER OF ATTORNEY FOR REISSUE APPLICATION

We, Robert H. Reid, John E. van Hamont, William R. Brown, Edgar C. Boedeker, and Curt Thies, hereby declare that we are citizens of the United States and that our residences are as stated below next to our names. We believe that we are the original joint inventors of the invention entitled MICROPARTICLE CARRIERS OF MAXIMAL UPTAKE CAPACITY BY BOTH M CELLS AND NON-M CELLS described and claimed in our original application No. 08/242,960, filed May 16, 1994, and the resulting United States Patent No. 5,693,343 which issued December 2, 1997 ("the '343 patent"), for which priority was claimed based on Ser. No. 867,301, filed April 10, 1992, Pat. No. 5,417,986 which is a continuation in part of Ser. No. 805,721, filed Nov. 21, 1991, abandoned, which is a continuation in part of Ser. No 690,485, filed April 24, 1991, abandoned, which is a continuation in part of Ser. No. 521,945, filed May 11, 1990, abandoned, which is a continuation in part of Ser. No. 493,597, filed March 15, 1990, abandoned, which is a continuation in part of Ser. No. 590,308, filed March 16, 1984, and for which invention a reissue patent is solicited.

We do not know and do not believe that the invention of the '343 patent was ever known or used in the United States before our invention thereof. Furthermore, we do not know and do not believe that the invention was patented or described in any publication in any country before our invention thereof, or more than one year prior to the original application. We do not know and do not believe that the invention was in public use or on sale in the United States more than one year prior to the original application. To the best of our knowledge and belief, this invention has

not been patented or made the subject of an inventors' certificate in any country foreign to the United States prior to the date of the original application on an application filed by us or our legal representatives or assigns more than 12 months before our original application.

We have reviewed and understand the contents of the attached specification, including the claims, as amended by the addition of new claims 8-24. We acknowledge the duty to disclose information of which we are aware and which is material to the examination of the application in accordance with 37 C.F.R. §§ 1.56(a) and 1.175(a) (7).

We believe that through error, without any deceptive intent, the '343 patent is partially inoperative or invalid by reason of the patentee claiming less than the patentee had the right to claim in the patent.

In particular, in the context of the invention, oil viscosity is the primary process parameter in determining the average distribution of particle size ranges of the microsphere diameter. Applicants were the first to invent a modified solvent extraction process for preparing microspheres of biodegradable polymer having a predetermined average particle size distribution such that, there is maximal uptake of the microspheres by both M Cells and non-M Cells, either in the villous epithelium or in the Peyer's patches follicle associated epithelium, when using the polymer as a carrier of immunogens for immunization in mammals. This has unexpectedly been accomplished by modifying the solvent extraction process for producing microspheres so that the average particle size distribution is controlled by altering the viscosity of the emulsion.

New claim 12 sets forth adjusting the viscosity that corresponds to a predetermined average particle size of microspheres to control the size of the microspheres. This feature alone is

distinguishable over the Tice '840 reference cited against Patentees in the Office Action dated July 11, 1995. Therefore, Patentees believe that the issued claims are much narrower than necessary because Patentees in error claimed less than they were entitled to. Thus, Patentees believe they are entitled to new claim 12 which is broader than claim 1. (New claim 12 is supported at column 3, lines 1-18 and column 4, lines 46-67, column 7, lines 31-33 and 49-54.)

Additionally, Patentees were the first to invent a process that initially lyophilizes the agent stabilizer matrix to make a hydrophilic matrix prior to dispersal of the matrix into the solvent in the process of the invention. This lyophilizing step stabilizes and isolates the agent being encapsulated from the solvents in the process. New claim 13 sets forth this step as well as the aspect of controlling the viscosity to correspond to a predetermined average particle size distribution of microspheres as discussed above. Tice '840 does not disclose this step. Tice requires direct dispersal or dissolving of the active agent into the same solvents being used to dissolve the polymer. Therefore, Patentees believe that the issued claims are much narrower than necessary because Patentees in error claimed less than they were entitled to. Thus, Patentees believe they are entitled to new claim 13 which is broader than claim 1. (New claim 13 is supported at column 3, lines 1-18 and column 4, lines 46-67 and column 5, line 5 through column 6, line 35, column 7, lines 31-33 and 49-54.)

Still additionally, the Patentees were the first to discover a composition or an immunostimulating composition of encapsulating microspheres of a biodegradable polymer that have an average particle size distribution wherein a majority of the microspheres will be taken up by the villous epithelium section of an intestines when administered as recited in new claims 17

and 19; or wherein a majority of the microspheres will be taken up by the Peyer's patch section of an intestine when administered as recited in new claims 18 and 22. The Tice '840 patent does not disclose these features and these aspects of the invention were not claimed in the patent for which reissue is requested. Therefore, Patentees, in error, claimed less then they are entitled to. (New claims 17, 18, 19 and 22 are supported at column 2, lines 47-67, Fig. 18, column 4, lines 33-37, column 8, lines 54-63, Tables 3 and 4.)

All of these possible errors arose without deceptive intent during prosecution of the application before the United States Patent and Trademark Office. Upon reviewing the issued claims at the direction of Patentees' new representative, we discovered the errors presented above and realized that the claims did not cover all of the subject matter that the we believe we are entitled to.

Therefore, by reason of the above-described errors, Applicants believe the original patent to be partly inoperative or invalid by reason of the patentees claiming less than patentees had the right to claim in the patent and the claims are possibly not broad enough to cover all aspects of the invention disclosed in the patent. The possible invalidity of the patent resulted from a failure by ourselves, the assignee and counsel to realize the totality of the subject matter that should have been claimed. By this reissue application, the identified errors are believed to be corrected.

All errors which are being corrected in the present reissue application up to the time of filing of this declaration arose without any deceptive intention on the part of the applicants.

Wherefore we request that we may be allowed to surrender, and we hereby offer to surrender, said U.S. Letters Patent No. 5,693,343 and request that Letters Patent be reissued to

ourselves and the assignee, The United States of America as represented by the Secretary of the Army, for the same invention upon the foregoing amended reissue application.

We hereby declare further that all statements made herein of our knowledge are true and that all statements made on information and belief are believed to be true. We further declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

We hereby appoint Elizabeth Arwine, Reg. No. 45,867 of the U.S. Army Medical Research and Materiel Command, 504 Scott Street, ATTN: MCMR-JA, Fort Detrick, MD 22702 and Caroline Nash (Reg. No. 36,329) and Marlana K. Titus (Reg. No. 35,843) of Nash & Titus, LLC, 3415 Brookeville Road, Suite 1000, Brookeville, Maryland 20833, (301) 924-9500 or (301) 924-9600 (all communications are to be directed to Nash & Titus, LLC) individually and collectively as our attorneys to prosecute this application and to transact all business in the Patent and Trademark office connected therewith and with the resultant Patent.

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